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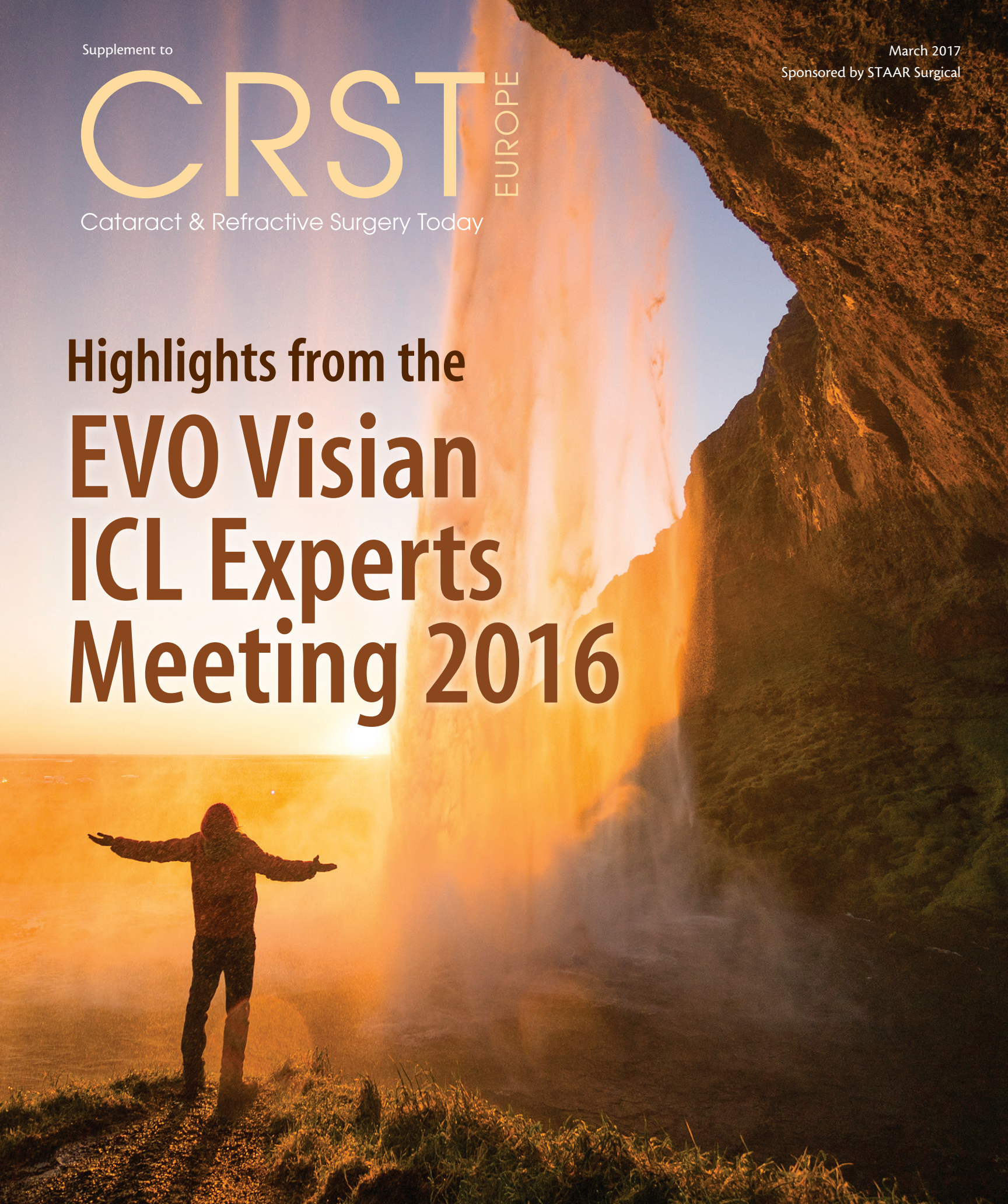


Highlights from the EVO Visian ICL Experts Meeting 2016

TREATMENT OF STABLE KERATOCONUS

Sequential intrastromal corneal ring segment and EVO Visian ICL implantation can be a winning combination.

BY JOSÉ F. ALFONSO, MD, PHD

I have, for many years now, relied on a multitude of therapies for the management of keratoconus. These therapies, which range from therapeutic approaches like intrastromal corneal ring segment (ICRS) implantation, CXL, and keratoplasty to refractive approaches like PRK, lensectomy, and phakic IOLs. In some cases, I have even combined treatments, of which the most common is ICRSs with a phakic IOL.

Most recently, I have studied the use of ICRSs with the Visian ICL Toric (now EVO Visian ICL Toric; STAAR Surgical), to address the needs of patients with stable keratoconus (grades 1–3). A similar treatment was first described by Coskunseven et al[1] in 2007. In that study, two patients with keratoconus and extreme myopia first received Intacs (Addition Technology), followed 6 to 10 months later with the Visian ICL Toric. Alternatively, in my procedure, I first implant the Keraring (Mediphacos), followed sequentially with implantation of the EVO Visian ICL 6 months later. To date, I have seen successful results with this approach in patients across the range of keratoconus phenotypes outlined in *Classification of Keratoconus*. This classification system is further explained in a doctoral thesis by Fernández-Vega Cueto.[2]

RETROSPECTIVE STUDY

In order to assess the visual and refractive results of the combination of ICRSs with the EVO Visian ICL for the treatment of stable keratoconus, I conducted an observational, longitudinal, retrospective study of 42 eyes of 30 patients.[3] The mean age of this population was 34.8 ±6 years (range, 21–43 years). All patients had keratoconus with coincident topographic and comatic axes, flattest keratometry (K) between 40.00 and 50.00 D, keratometric astigmatism lower than 9.00 D, and significant myopia or hyperopia. Preoperatively, the mean UDVA was 0.1 ±0.1 (range, 0.1–0.3); the mean CDVA was 0.6 ±0.2 (range, 0.2–0.9); the mean sphere was -8.00 ±6.60 D (range, -17.25 to 3.25 D); and the mean refractive cylinder was -3.82 ±1.90 D (range, -7.00 to -1.00 D).

In all cases, the patient first received the 5-mm Keraring model, and a corneal thickness implantation zone of at least 400 µm was respected. With this treatment modality, the mean UDVA, CDVA, sphere, and refractive cylinder improved to 0.2 ±0.2 (range, 0.1–0.7), 0.8 ±0.2 (range, 0.4–1.0), -6.26 ±6.90 D (range, -20.00 to 3.50 D), and -1.99 ±1.10 D (range, -4.00 to 0.00 D), respectively.

Then, 6 months after Keraring implantation, all patients received the EVO Visian ICL. During this second procedure, one or two 3.2-mm opposite clear corneal incisions (CCIs) were also created, in order to address the keratometric astigmatism. After this treatment, the mean

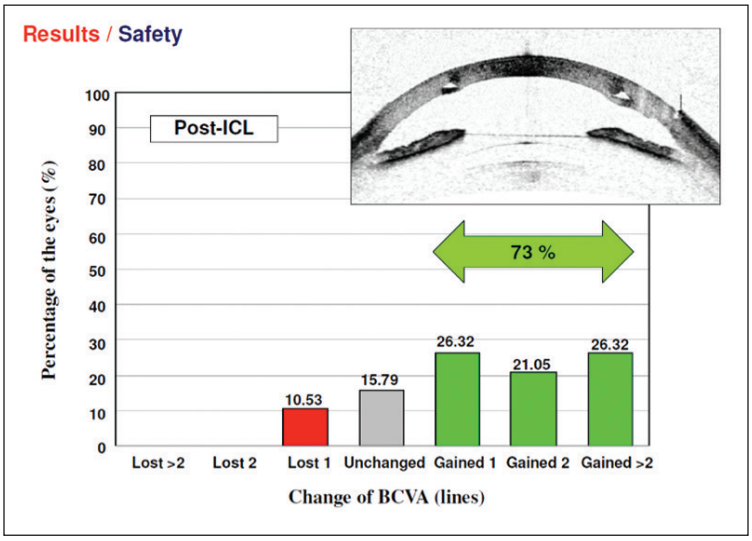


Figure 1. Changes in BCVA after EVO Visian ICL implantation.

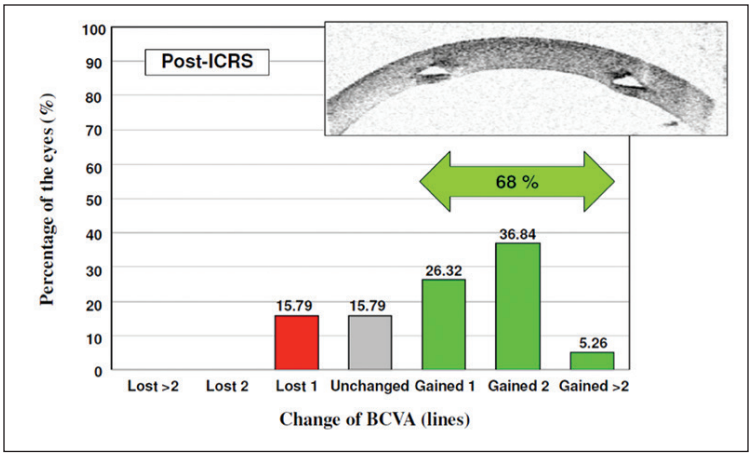


Figure 2. Changes in BCVA after ICRS implantation only.

UDVA, CDVA, sphere, and refractive cylinder once again improved, to 0.6 ±0.2 (range, 0.2–1.0), 0.8 ±0.1 (range, 0.5–1.0), -0.21 ±0.70 D (range, -2.00 to 1.50 D), and -0.88 ±0.70 D (range, -2.00 to 0.00 D), respectively.

Regarding safety of the combined procedure, 73% of patients gained 1 to 3 lines of BCVA, whereas 15.79% neither gained nor lost and only 10.53% lost 1 line of BCVA (Figure 1). As a comparison, 68% of patients had gained 1 to 3 lines of BCVA after the initial ICRS treatment, 15.79% remained unchanged, and 15.79% lost 1 line (Figure 2). What is especially interesting is that the percentage of patients who gained 2 or more lines

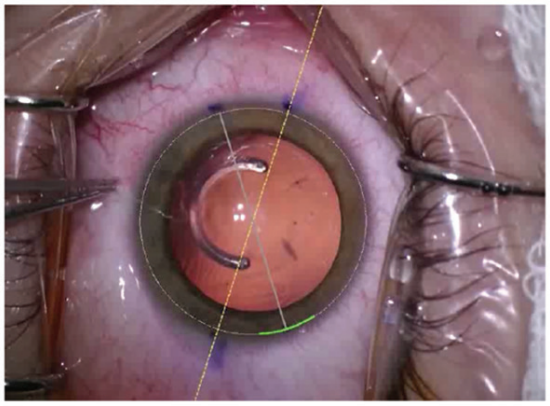


Figure 3. In this case, the 210º ICRS was placed at 90º, followed by the implantation of the EVO Visian ICL Toric.

increased from 5.26% after the ICRS treatment to 26.32% after the EVO Visian ICL was implanted.

The refractive predictability in both cylinder and sphere corrections was good, with 78% of patients within ±1.00 D of intended correction for sphere and 61% for cylinder after ICL implantation combined with CCI creation.

A SECOND COMBINATION: ICRSs, ICL TORIC

Given our excellent outcomes with the combination of ICRSs, EVO Visian ICL, and opposite CCIs in patients with stable keratoconus, and given the excellent results with the EVO Visian ICL Toric both in a standalone procedure[4] and in combination with CXL,[5] we recently decided to also try combining ICRSs with the EVO Visian ICL Toric. We performed our first cases in 2016, of which one is described herein.

A 30-year-old man with stable keratoconus, steep K of 50.00 D, and refraction -6.00 -6.00 X 150º presented for surgery. His UDVA and CDVA were 0.16 and 0.6, respectively. After we implanted a 210º Keraring, he had a refraction of -5.00 -4.00 X 125º, with UDVA and CDVA of 0.3 and 0.7, respectively.

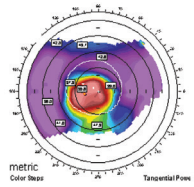
Six months later, we implanted a EVO Visian ICL Toric lens with powers of -10.50 D sphere and 5.50 D cylinder (Figure 3). Once again mean UDVA, CDVA, sphere, and refractive cylinder improved postoperatively, to 0.6, 0.8, -1.00 D, respectively.

Although no long-term follow-up is available and the procedure has only been performed on a small number of patients to date, our preliminary results are encouraging. I look forward to presenting more results on this combination in more patients in the near future.

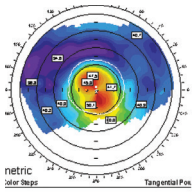
CONCLUSION

With many therapies available for the treatment of keratoconus, it can be hard for surgeons to pinpoint what strategy is best. In my experience, the combination of ICRSs and the EVO Visian ICL spherical and toric lenses is an effective and safe procedure in patients with stable keratoconus. The ICRS can be used to target corneal irregular astigmatism, and the ICL can be used to target the residual sphere and corneal astigmatism.

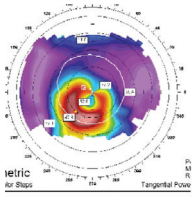
CLASSIFICATION OF KERATOCONUS



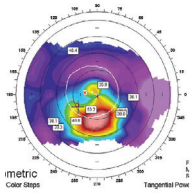
NIPPLE
Central-paracentral with high asphericity



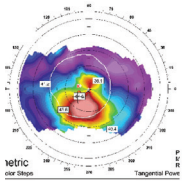
BOWTIE
Central with regular astigmatism



CROISSANT
Para-pericentral with coincident topographic and coma axes



DUCK
Paracentral with no coincident topographic and coma axes



SNOWMAN
Paracentral with perpendicular topographic and coma axes

I urge surgeons who are considering this strategy to keep at least 6 months in between the sequential treatments. ■

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- Financial disclosure: None acknowledged

FIRST CLINICAL OUTCOMES WITH THE EVO+ VISIAN ICL

The intraoperative behavior of the lens, its vault, and its refractive precision are all similar to those of the EVO.

BY JAIME ARAMBERRI, MD

For many years now, the EVO Visian ICL (previously known as the Visian ICL V4c; STAAR Surgical) has been my elective procedure of choice for young patients between the ages of 21 and 45 years who desire refractive correction for -0.50 to -18.00 D myopia and, with the toric version of the lens, up to 6.00 D astigmatism. In my patients, I have consistently seen excellent postoperative outcomes, with high patient satisfaction and little to no visual disturbances. When visual disturbances had been noted by patients, in many cases, it was due to their large pupil size, which caused them to experience a diffraction effect that most commonly presented as halos.

Now, variations of the EVO with an expanded optic, the EVO+ and EVO+ Toric, are available to better accommodate the ocular anatomy of patients with larger pupils. This increase in the lens' surface (up to 20% depending on the lens power), creates more pupil coverage, and may improve meso-scotopic vision quality, and, therefore, likely results in a decrease of the diffraction effect.

The only difference between the EVO and EVO+ lenses is, indeed, the expanded optic of up to 6.1 mm in optic zone diameter. Both are made with the company's proprietary advanced collamer lens material, which is biocompatible with the eye, UV-A protectant, and soft and pliable to promote easy implantation. As a result, there is no need to modify one's surgical technique or power calculation and sizing methods when implanting the EVO+.

PERSONAL EXPERIENCE

Since 2011, I have been implanting models of the ICL that incorporate the KS-Aquaport*, a hole in the center of the lens that eliminates the need for an iridectomy or iridotomies. In the past 6 years, I have implanted more than 700 ICLs. Most recently, in February 2016, I implanted the very first EVO+ Visian ICL. Thus far, results with this lens have been just as good as they were with the EVO Visian ICL, and refractive accuracy and visual quality of the lens have been impressive. My experience is not unique; in their study, Domínguez-Vincent et al[1] found that the optical quality of the EVO+ was comparable not only to the EVO but also to the natural crystalline lens. They also found no significant differences in higher-order aberrations between the lenses, including total root mean square, coma, trefoil, tetrafoil, and secondary astigmatism in any power and aperture. They had analyzed lens models in four powers over 3- and 6-mm pupil sizes.

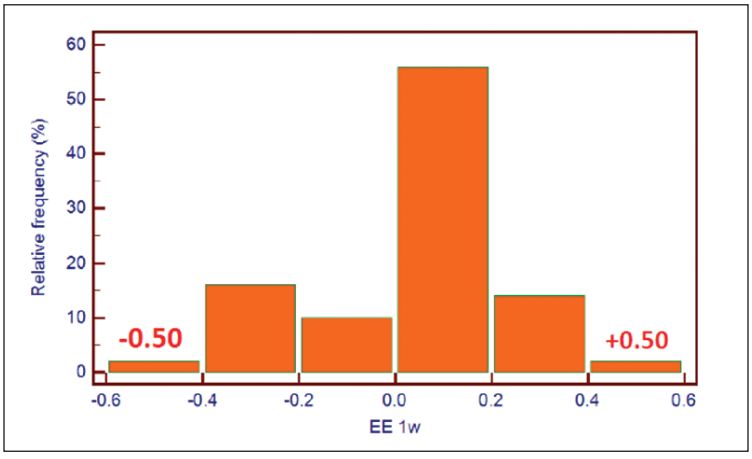

Figure 1. Efficacy at 1 week postoperative: 100% of eyes were within ±0.50 D spherical equivalent.

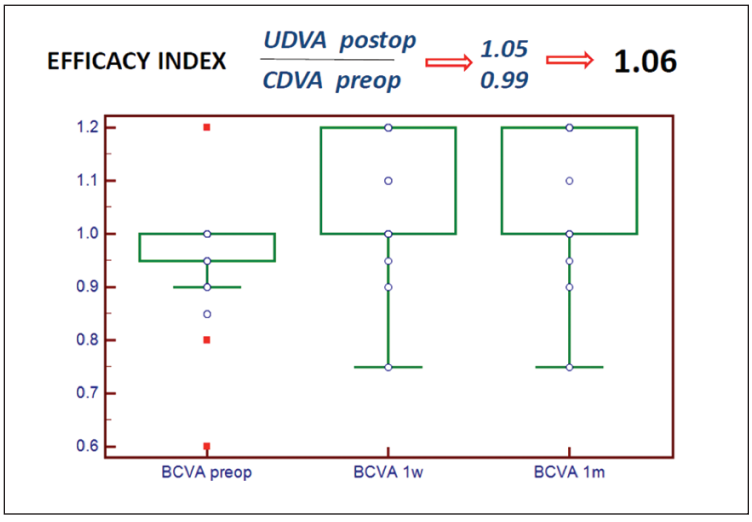

Figure 2. BCVA at 1 week and 1 month postoperative.

I recently conducted a study of 50 eyes of 27 patients who received the EVO+ Visian ICL or EVO+ Visian ICL Toric at my practice

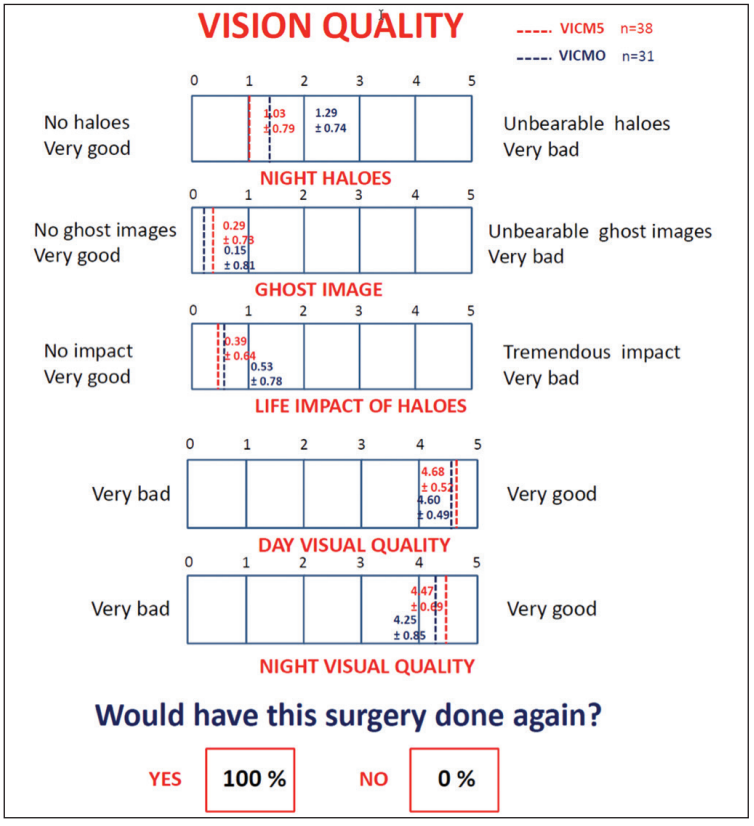

Figure 3. Patient satisfaction survey: vision quality.

between February 23 and August 23, 2016. A lens with an overall size of 12.6 mm was implanted in 12% of eyes, of 13.2 mm in 80%, and of 13.7 mm in 8%, and the mean spherical equivalent was -8.89 ±2.36 D (range, -5,00 to -14.00 D). The toric ICL was indicated if the eye presented with at least 1.25 D astigmatism.

In all cases, the lens was implanted via a 2.75-mm incision on the steep axis. I used an OVD with a low molecular weight and viscosity, as recommended by STAAR Surgical. Postoperative follow-up including refraction, biomicroscopy, IOP, and vault was scheduled for 1 day and 1 and 4 weeks after surgery.

RESULTS

Efficacy. At 1-week postoperative, 100% of eyes were within ±0.50 D of intended correction (Figure 1). As means of comparison, in a sampling of eyes that received the EVO Visian ICL in 2013, 98.9% were within ±1.00 D of intended correction, and 90.11% were within ±0.50 D. The EVO+ lens also boasted excellent BCVA at 1-week and 1-month postoperative (Figure 2), with a safety index of 1.12 at 1-week postoperative (Table 1). In the same sampling of EVO eyes from 2013, the safety index at 6 months postoperative was 1.20.

IOP. When we looked at mean IOP, at 1-week postoperative, it was slightly higher than it was preoperatively (18.48 vs 16.62 mm Hg, respectively). However, by the 1-month follow-up, the mean IOP had returned to preoperative levels (16.65 vs 16.62, respectively).

TABLE 1. SAFETY INDEX OF THE EVO+ VISIAN ICL AT 1-WEEK POSTOPERATIVE

DCVA LINE CHANGE	N	%	Cumulative Freq
-0.10	1	2	2
0	17	34	36
0.10	28	56	92
0.20	4	8	100
0.30	0	0	100
Total	**91**	**100**	

Vault. The mean vault at 1-month postoperative was 611.38 ±182.07 µm, which was slightly better than the mean vault that we had been able to achieve with the standard EVO Visian ICL. In the majority of eyes that received the EVO+ (92.5%), the vault was between 300 and 1,000 µm. In one eye with a low vault (280 µm), the lens had been implanted vertically. Once rotated to the horizontal meridian, the vault increased to 680 µm. In another case, a high vault of 1,160 µm was found, and the lens was rotated at a later time to the horizontal meridian. The final vault in that case was 740 µm.

Patient satisfaction. On a scale of 0 to 5 (0 = very good, 5 = very bad), patients who received the EVO+ Visian ICL were asked to rate their visual quality with regards to the presence of halos and ghost images and the impact they have had on visual function and life tasks. Scores were then compared to those reported by patients who had previously received the EVO model (Figure 3). Like the EVO, patients with the EVO+ seemed to experience halos early postoperatively but reported that they improved over time. By 1-month postoperative, all patients were happy with their visual outcomes.

In three patients included in the study of the EVO+, an EVO lens had previously been implanted in the contralateral eye. One of these patients, who was emmetropic in both eyes and had a 6.5-mm scotopic pupil, reported better mesopic visual quality in the eye that received the EVO+. The other two patients reported no differences in visual quality or in overall satisfaction between their eyes.

CONCLUSION

I have reported no significant difference in the folding, cartridge loading, unfolding, and footplate manipulation between the EVO+ and EVO Visian ICLs. Likewise, there has been no difference with the vault and refractive precision of the lenses. What I have noticed, however, is an improvement in visual quality due to the EVO+'s wider optical zone decreasing the diffraction effect. At present, I only implant the EVO+ Visian ICL in patients who present with -14.00 D myopia or less. ■

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- Financial disclosure: Consultant (STAAR Surgical)

*The KS-AquaPORT was named after and developed in cooperation with Kimiya Shimizu, MD, of Japan.

ENHANCING NIGHT VISION WITH THE EVO VISIAN ICL

A comparison of night vision and contrast sensitivity after phakic IOL implantation and LASIK.

BY GREGORY D. PARKHURST, MD, FACS

To date, more than 800,000 US military personnel have undergone successful refractive surgery as part of the Warfighter Refractive Eye Surgery Program (WRESP), an initiative designed to reduce the limitations posed by corrective eyewear in combat arms soldiers. Although a majority of the procedures performed as part of the WRESP have been excimer laser surgery, the EVO Visian ICL (STAAR Surgical) is available in selected US Army WRESP centers to patients who are contraindicated for a laser-based correction procedure such as LASIK and PRK.

BACKGROUND

Both laser- and lens-based solutions to refractive errors can effectively reduce the need for corrective eyewear in the general public and in combat arms soldiers. However, some vision problems after LASIK have been cited in the literature. Namely, low luminance vision and contrast sensitivity can be diminished after surgery. More recently, the use of wavefront technology in excimer laser ablations has resulted in less degradation of low luminance vision and contrast sensitivity;[1] yet it has been shown that the EVO Visian ICL induces significantly fewer higher-order aberrations (HOAs) and improves contrast sensitivity when compared with wavefront-guided LASIK.[2] Furthermore, the EVO Visian ICL has been found to be safer and more effective than LASIK in treating low and moderate to high myopia.[3]

To the best of my knowledge, no study has fully compared the quality of night vision in patients after wavefront-optimized LASIK to that in patients who have received a phakic IOL. Therefore, my colleagues and I recently compared night vision performance in patients who had undergone wavefront-optimized LASIK with the WaveLight Allegretto (Alcon) to those implanted with the EVO Visian ICL. In order to test vision in conditions of low luminance, a simulated night vision goggle (NVG) environment was used. Below I share our results.

STUDY DESIGN

A total of 95 eyes (LASIK group, n=48; ICL group, n=47) with -3.00 to -11.50 D myopia and no more than 2.25 D astigmatism were enrolled. All patients had requested refractive surgery, and permission was granted by his or her military commander. Those with primary open-angle glaucoma or cataract were not eligible.

After a screening examination with a WRESP optometrist, all patients attended a group briefing session in which the risks, benefits, and alternatives of refractive surgery were discussed. Upon completion, each patient had an individual consultation with a surgeon. If eligible for laser vision correction, the patient was free to select between LASIK and PRK.

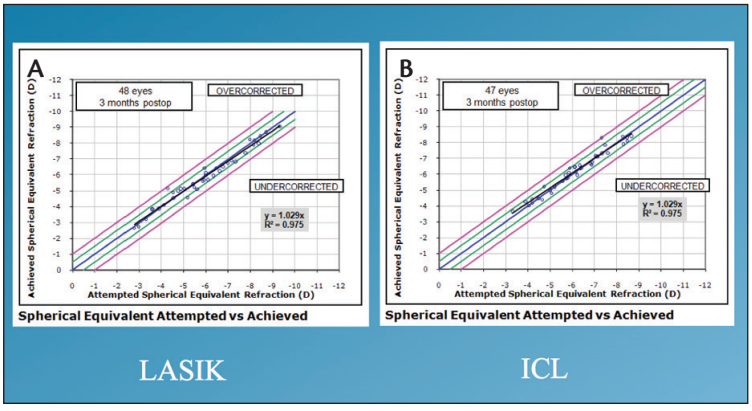

Figure 1. Attempted versus achieved spherical equivalent in the LASIK (A) and ICL (B) groups.

If ineligible due to abnormal topography, thin central corneal thickness, or low residual keratometry readings, the patient was considered for the EVO Visian ICL. Only those with a healthy endothelium were considered candidates for the ICL. In the ICL group, a laser peripheral iridotomy was performed 2 weeks prior to lens implantation. Then, during lens implantation, the primary incision was placed temporally or on the steep axis of refractive cylinder; no astigmatic treatments such as limbal relaxing incisions or bioptics were performed.

Both preoperatively and 1 and 3 months postoperatively, visual performance was assessed with the Rabin Super Vision Test (Precision Vision), a program that simulates the chromaticity and luminance of a NVG display at 25% moonlight. At those same time intervals, total HOAs also were measured with the WaveLight Topolyzer (Alcon). Both sets of tests were administered by a certified ophthalmic technician specifically blinded to the procedure, and the test results were interpreted by an ophthalmologist blinded to the procedure.

RESULTS

Spherical equivalent. The attempted versus achieved spherical equivalent results are presented in Figure 1. When we looked at refractive accuracy, what we found is that, at 3 months postoperatively, 100% of

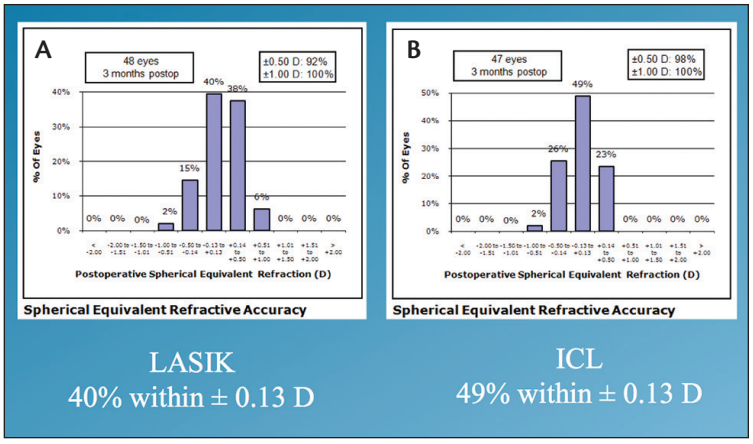

Figure 2. Spherical equivalent in the LASIK (A) and ICL (B) groups.

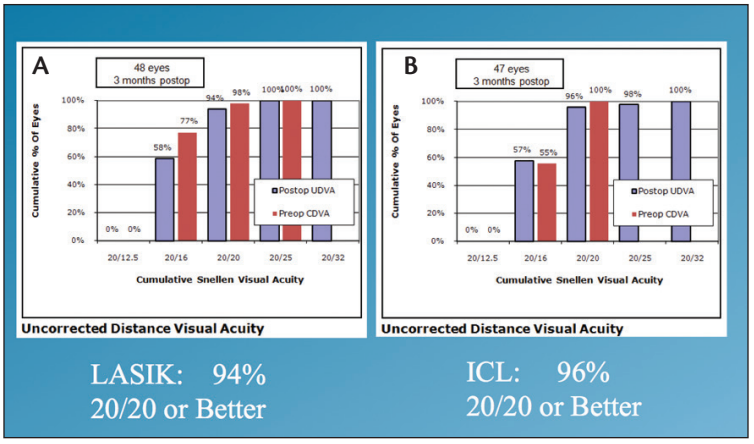

Figure 3. UDVA in the LASIK (A) and ICL (B) groups.

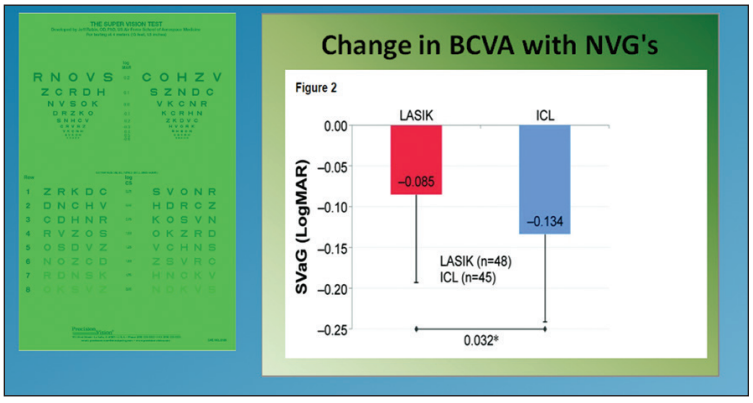

Figure 4. Mean within eye change in BCVA under low luminance levels.

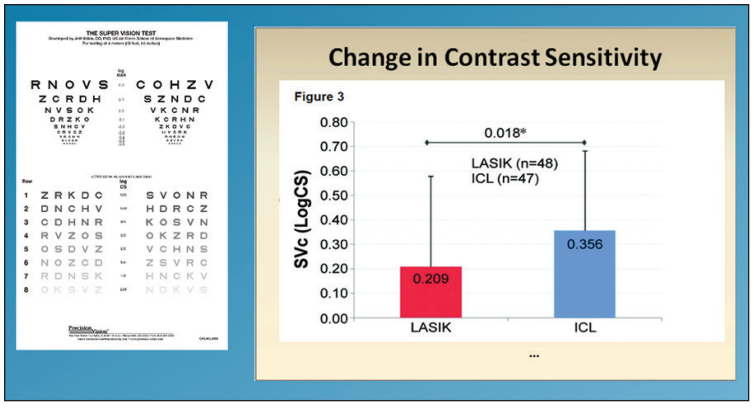

Figure 5. Mean within eye change in contrast sensitivity under low luminance levels.

patients enrolled in the study were within ±1.00 D of intended correction. Furthermore, 49% of the ICL group and 40% of the LASIK group were within ±0.13 D (Figure 2). Looking at ±0.50 D, 98% of the ICL group and 92% of the LASIK group were within this range.

Visual acuity in normal conditions. Visual acuity (logMAR) and contrast sensitivity were presented on a single chart under both normal light and low luminance levels with the Rabin Super Vision Test. At 3 months postoperatively, 95% of all eyes were 20/20 or better in normal light conditions. When each group was analyzed separately, 96% of the ICL group and 94% of the LASIK group had a UDVA of 20/20 or better (Figure 3).

Low luminance visual acuity. At 3 months postoperatively, low luminance BCVA had significantly improved in the ICL group but not in the LASIK group (Figure 4). Furthermore, improvement in contrast sensitivity in low luminance conditions was seen in both groups; however, these improvements were significantly greater in the ICL group (*P*=.04; Figure 5).

CONCLUSION

Given that low luminance visual acuity and contrast sensitivity significantly improved in combat arms soldiers after implantation of the EVO Visian ICL and that these outcomes were significantly better than those observed after wavefront-optimized LASIK, phakic IOLs are an interesting option for the correction of refractive errors. This is especially true in patients who require excellent night vision, such as the population included in our study. In addition to visual performance, stability of the ICL is another important consideration included in the risk/benefit analysis for refractive surgery. ■

**Author's Note: The use of Nightfighter data and information does not imply or constitute US Department of Defense endorsement.*

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LENS OR LENS PLUS LASER?

Both clinically and financially, the EVO Visian ICL is the better choice compared with bioptics.

BY MARTIN BECHMANN, MD

There is no doubt that we refractive surgeons are masters of our trade. We stay abreast of the latest advancements and the newest procedures, and we vow to offer patients what we believe are the best and most effective treatments to obtain the refractive outcomes they desire. Sometimes, however, we must take a step back from this and ask ourselves if a given treatment or trend measures up not only clinically but also financially.

In the same vein, recently, my colleagues and I worked with a consultant to conduct a profitability analysis of our Smile Eyes center in Munich, Germany. Of the 11 Smile Eyes centers across Germany and Austria, this is our busiest, as approximately 1,200 refractive procedures are performed here annually. Among the total number of refractive procedures, small incision lenticule extraction (SMILE) and femtosecond LASIK account for 70% of our volume. These procedures are preferred in patients with refractive errors between 3.00 and -8.00 D. The other 30% of our total refractive surgery volume is made up of refractive lens exchange (20%) and phakic IOL implantation (10%). These procedures are preferred in patients with high hyperopia and high myopia and in patients with irregular corneas. Looking at only phakic lens implantation procedures, in some cases we implant the lens as a standalone procedure and in others in combination with a laser treatment, in what is referred to as a *bioptics* procedure.

One of the main reasons that we initially offered bioptics to our patients was because the AcrySof Cachet (Alcon), the phakic IOL that we had been previously using for years, was not available in a toric version. Even after we switched to the Visian ICL (now EVO Visian ICL; STAAR Surgical), a phakic IOL that is available in a toric version, we had continued to offer bioptics as an option for our patients. The reason for this was that we first wanted to gather some clinical experience with the toric ICL. After we found out that this lens was stable and that results were excellent, we only offered bioptics to patients as a more cost-effective solution due to the higher price of the toric implant.

But was it still financially worthwhile for our practice to continue offering this package? This is what we set out to discover through the profitability analysis. One thing to point out, however, is that we did not want to modify in any way our indications for surgery; we wanted to continue treating refractive errors between 3.00 and -8.00 D with a laser-based procedure and high hyperopia and high myopia and patients with irregular corneas with a lens-based procedure.

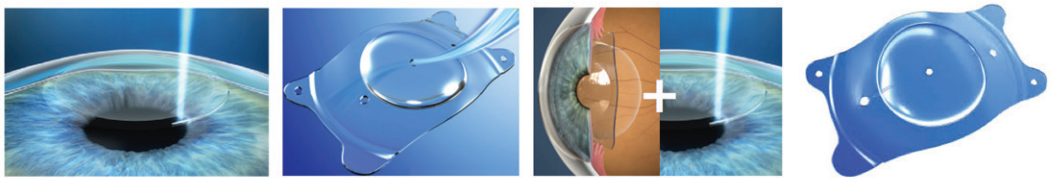
ANALYSIS

Conducting the profitability analysis required us to look at several things: our pricing strategy, our operational process scheme, and the types of costs associated with our process.

Pricing strategy. First, we broke down our pricing strategy per eye (see *Smile Eyes: Refractive Surgery Pricing*). When we originally devised our price points, we placed a logical gap between pricing for the spherical EVO Visian ICL and bioptics procedures (both at €3,000/eye) and pricing for the EVO Visian ICL Toric procedure (€3,500/eye). This was purely due to the higher cost of the toric version of the lens. It did not take into account any additional costs, such as personnel or equipment.

Simplified process scheme. We then outlined our simplified process scheme, which included marketing, patient consultations,

SMILE EYES: REFRACTIVE SURGERY PRICING



SMILE / Femto-LASIK	ICL spheric 850 €	Bioptics 850 €	ICL toric 1300 €
2.500 € /eye	3.000 € / eye	3.000 € / eye	3.500 € / eye

TABLE 1. PERSONNEL COST PER MINUTE FOR LENS-BASED PROCEDURES

		Technician	OR-Nurse	Ophtalmologist	Anaesthetist	Surgeon
Personnel cost p.a.						
Gross salary		27.600 €	28.800 €	120.000 €	120.000 €	200.000 €
Ancillary wage costs	19,50%	5.382 €	5.616 €	23.400 €	23.400 €	39.000 €
Total personnel cost		32.982 €	34.416 €	143.400 €	143.400 €	239.000 €
Working hours per week		38,5	38,5	38,5	38,5	38,5
Working days per week		5	5	5	5	5
Minutes per day (5 day working week)		462	462	462	462	462
Calculation of available working time p.a.		Days / Minutes	Days / Minutes	Days / Minutes	Days / Minutes	Days / Minutes
Working days in Munich (2016)		250 / 115.500	250 / 115.500	250 / 115.500	250 / 115.500	250 / 115.500
Training		2 / -924	2 / -924	5 / -2.310	5 / -2.310	5 / -2.310
Vacation		30 / -13.860	30 / -13.860	30 / -13.860	30 / -13.860	30 / -13.860
Sick days		15 / -6.930	15 / -6.930	5 / -2.310	5 / -2.310	5 / -2.310
Available working time (minutes / year)		93.786	93.786	97.020	97.020	97.020
Utilisation		75%	75%	75%	75%	75%
Calculated available working days (minutes / year)		70.340	70.340	72.765	72.765	72.765
Calculated cost rate						
Cost rate per OR-minute	€ / Min.	0,47	0,49	1,97	1,97	3,28

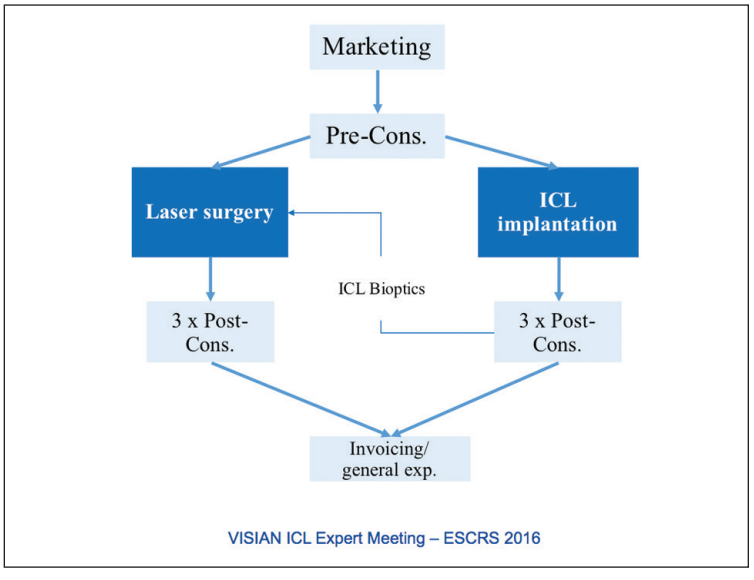


Figure 1. A simple outline of the process scheme used by Smile Eyes.

the surgery itself, postoperative follow-up and care, and invoicing (Figure 1).

Types of costs. The third and most time-consuming part of the profitability analysis was to determine the various costs associated with each procedure. We broke this down into four components: personnel costs, including the surgeon, anesthesiologist, ophthalmologist, theatre nurse, and technician; occupancy costs, including the operating room, consultation, and rent and incidental rent expenses; equipment costs, including the purchase depreciation and maintenance costs for the following equipment: femtosecond laser, excimer laser, microscope, and phacoemulsification machine; and material costs, including the EVO Visian ICL, expendable materials, and treatment packs.

Once we broke down the personnel cost per minute (Table 1), we were then able to compare the amount of money we spent per lens-based procedure (EVO Visian ICL, bioptics, and EVO Visian ICL Toric) across all components. Whereas we spent roughly the same amount of money on marketing, administration, and occupancy for all three procedures, the personnel and equipment costs were highest with the bioptics procedure, and the material costs were highest in the EVO Visian ICL Toric procedure (Figure 2). When we looked at the total costs and profit associated with each procedure, we found that the bioptics procedure cost us the most and produced the smallest profit margin (Figure 3). The profit margins for both of the EVO Visian ICL procedures were similar.

LESS OF A PROFIT

Through our profitability analysis, we discovered that we were making only €150/eye with the bioptics procedure. Although still a profit, it was significantly less of a profit than we were making with both ICL procedures. We were quite surprised by that, and, in the end, we decided against continuing to offer patients the option of a bioptics procedure.

Although the profitability analysis is unique to our clinic—because

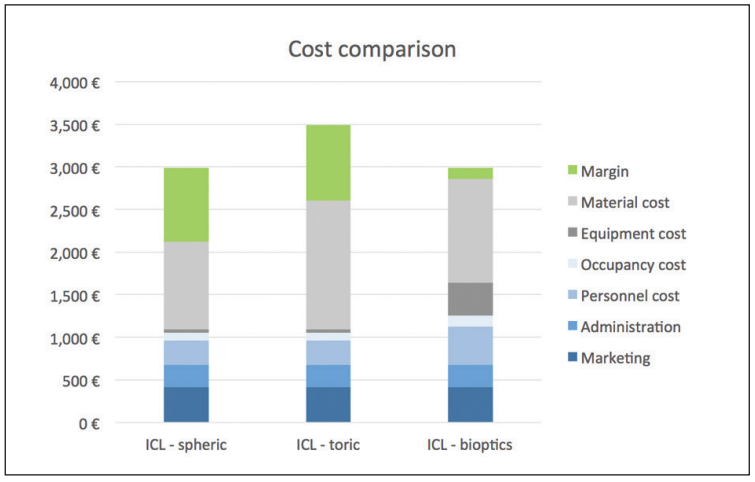


Figure 2. Cost comparison of three refractive surgery procedures: EVO Visian ICL, EVO Visian ICL Toric, and bioptics (combination ICL/laser vision correction).

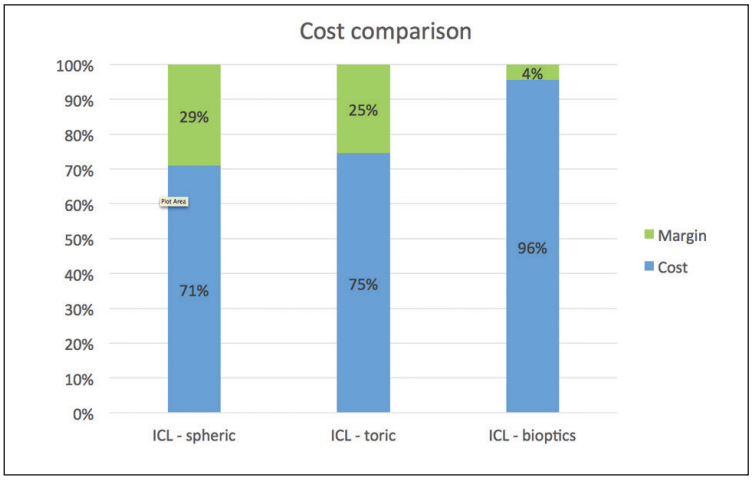


Figure 3. Profitability margins for the three procedures.

of our own pricing strategy and our own personnel, occupancy, equipment, and material costs—the overall message that can be extrapolated is this: offering the EVO Visian ICL Toric instead of bioptics can be a more profitable strategy.

CONCLUSION

The bottom line continues to be that just like any other refractive surgery practice, we do what is best for the patient. That, for us, is the EVO Visian ICL and EVO Visian ICL Toric. With this strategy, we can offer patients correction of their refractive error in a single treatment, which makes more sense not only for the patient but financially for our practice as well. ■

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- Financial disclosure: None acknowledged

VISUAL QUALITY WITH THE EVO VISIAN ICL

Patients achieve stable visual quality, decrease in HOAs within 1 month after implantation.

BY XIAOYING WANG, MD, PHD

In China, where I practice, the China Food and Drug Administration (CFDA) approved the Visian ICL V4c and the Visian ICL V4c Toric (now EVO Visian ICL and EVO Visian ICL Toric; STAAR Surgical) in October 2014. From my point of view, the approval was supposed to be fairly easy, as the addition of the KS-Aquaport—a hole in the center of the lens that is designed to restore more natural aqueous flow to the eye—made the need for peripheral iridotomy/iridectomy in conjunction with the surgery obsolete. And, in my personal experience, the lens continued to provide my patients with the same excellent visual outcomes postoperatively.

Just one short month after the CFDA approved these lenses, I was fortunate enough to implant the first toric lens of this kind in a 27-year-old man who worked as a teacher. Even from that early experience, I was extremely impressed with the visual quality that the EVO Visian ICL can provide. This specific patient had a refraction of -7.50 -2.00 X 165° OD and -10.50 -2.25 X 165° OS preoperatively, with central corneal thicknesses of 501 µm OD and 506 µm OS. His visual acuity was 0.9 logMAR OU. After surgery, the patient's visual acuity improved to 1.2 logMAR OU, and he had no pain and no complaints of glare or halos.

In the following years, I continued to see consistently excellent results with the lens that is now known as the EVO Visian ICL. In addition to a low incidence of glare and halos postoperatively, it seemed as if patients did not complain of visually disturbing higher-order aberrations (HOAs) and were able to achieve highly stable optical and retinal image quality.

VISUAL QUALITY ASSESSMENTS

In attempt to better assess these three components of visual quality (HOAs, intraocular scattering and optical quality, and glare and halos) after EVO Visian ICL implantation, I decided to conduct a study of my past patients.

HOAs. The mean age of patients (n=17) included in my evaluation of HOAs after EVO Visian ICL implantation was 26.76 ±5.15 years (range, 20–37 years). Preoperatively, the mean spherical equivalent (SE) in this group of 34 eyes was -12.24 ±3.30 D (range, -5.50 to -18.00 D). Coma, trefoil, spherical aberrations, and total HOAs in each patient were measured preoperatively and at 1, 3, 6, and 12 months postoperatively. In short, all four measurements significantly decreased after implantation of the EVO Visian ICL, both at 4- and 6-mm pupil sizes (Figure 1). And, from 1 month to 1 year postoperatively, all measurements were relatively stable, again both at 4- and 6-mm pupil sizes (Table 1).

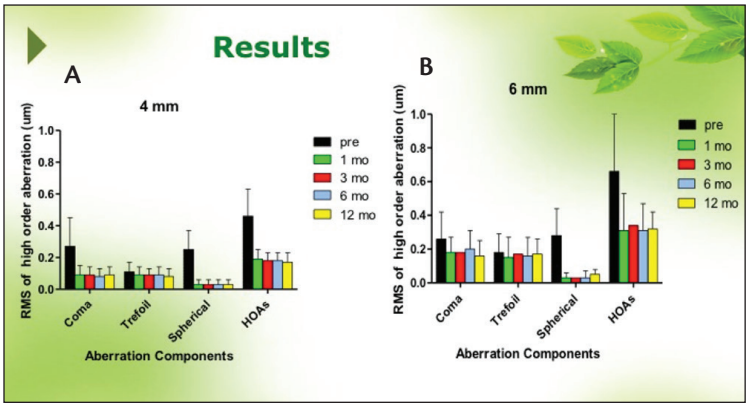
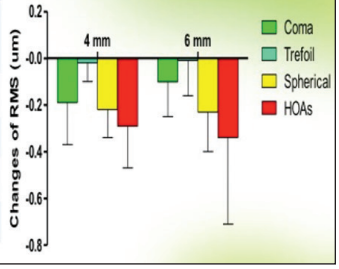


Figure 1. Coma, trefoil, spherical order aberrations, and HOAs at 4-mm (A) and 6-mm (B) pupil sizes.

TABLE 1. DIFFERENCE IN THE PRESENCE OF HOAs: PREOPERATIVELY TO 1 YEAR POSTOPERATIVELY

	Changes		P-value	
Aberration Components	4 mm	6 mm	4 mm	6 mm
Coma	-0.19±0.18	-0.10±0.15	<0.001	<0.001
Trefoil	-0.02±0.08	-0.10±0.15	0.122	0.619
Spherical	-0.22±0.12	-0.23±0.17	<0.001	<0.001
HOAs	-0.29±0.18	-0.34±0.37	<0.001	<0.001



Intraocular scattering and optical quality. In the group of 35 patients with moderate to high myopia included in my evaluation of intraocular scattering and optical quality, the mean age was 28.13 ±6.05 (range, 18–40 years*) and the mean preoperative SE was -12.24 ±3.31 D (range, -5.50 to -20.50 D). Refractive outcomes and optical quality was measured in 35 eyes at 1 and 3 months postoperatively with the OQAS II (Visiometrics), a double-pass optical quality analysis system. As seen in Table 2, patients achieved excellent optical quality by 1 month postoperatively, and that optical quality was stable through 3 months postoperatively. We also found better retinal image quality and lower intraocular scattering in the eyes with lower myopic errors.

*STAAR Surgical's recommended age range is 21–45 years.

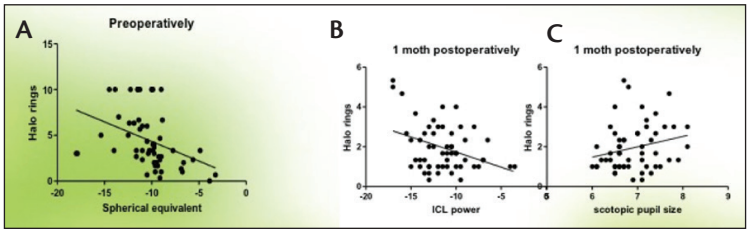


Figure 2. Preoperatively, halo size negatively correlated to SE (A); postoperatively, it correlated negatively to ICL power (B) and correlated to scotopic pupil size (C).

TABLE 2. OPTICAL QUALITY: 1 AND 3 MONTHS POSTOPERATIVELY

	1 Month		3 Months		
Parameters	**Mean**	**SD**	**Mean**	**SD**	**P Value**
MTFcutoff (cpd)	38.49	10.35	37.64	9.74	.474
Strehl Ratio	0.22	0.07	0.21	0.06	.301
OV100%	1.28	0.35	1.25	0.32	.475
OV20%	1.30	0.43	1.25	0.39	.283
OV9%	1.30	0.47	1.24	0.44	.264
OSI	1.00	0.83	0.98	0.71	.987

Glare and halos. I evaluated the presence of glare and halos in 56 eyes of 28 patients with a mean age of 25.46 ± 6.48 years (range, 18–45 years). The preoperative SE in this group was -10.28 ±2.79 D (range, -3.25 to -18.00 D). The MonCv3 Vision Monitor (Metrovision), a multifunctional perimeter, was used to detect glare and halos preoperatively and at 1 week and 1 month postoperatively. Looking into the MonCv3, patients watched three radial lines, each containing 10 letters, emerge from the periphery toward the glare surface. Also visible were 10 rings at intervals of 33 minutes of arc and a distance of 2.5 m. Using three different luminance levels (1, 5, and 100 cd/m^2) to represent night, dusk, and daytime, respectively, optotypes were presented on the screen at a distance of 2.5 m.

All patients reported considerable glare at the initial preoperative assessment, specifically because of the thick spectacle lenses required for the correction of moderate to high myopia. Although glare continued to be obvious to patients at 1 week postoperatively in both night and dusk luminance levels, it was alleviated by 1 month postoperatively. This result indicates that patients can adapt to glare, without any additional treatments, shortly after implantation of the EVO Visian ICL.

Regarding halos, whereas preoperatively the halo size negatively correlated to the SE, postoperatively, it negatively correlated to the power of the EVO Visian ICL and correlated to the scotopic pupil size (Figure 2).

STUDY CONCLUSIONS

From the studies of HOAs, intraocular scattering and optical quality, and glare and halos after EVO Visian ICL implantation, I have concluded that implantation of this phakic lens is safe and effective and that visual quality is stable postoperatively in patients with moderate to high myopia. Furthermore, my patients have all been able to attain excellent and stable postoperative optical within 1 month after lens implantation, as well as a decrease in the presence of HOAs.

Although patients with lower myopic errors tended to achieve better retinal image quality and lower intraocular scattering postoperatively than those with higher errors in these studies, I do believe that the EVO Visian ICL is an excellent choice for any patient who presents with moderate to high myopic errors. I have witnessed the incredible outcomes that all of my patients have achieved, regardless of their preoperative refractions, with many exclaiming that the EVO Visian ICL has changed their lives. It is for these reasons that I will continue to enthusiastically recommend the EVO Visian ICL to my patients when indicated. ■

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